REMARKS/ARGUMENTS

This Amendment accompanies a Request for Continued Examination and responds to the issues raised in the Official Action of May 23, 2006.

Discussion of Claim Amendments/New Claims

Claims 71-93 are active, wherein new Claim 71 is based on former claim 43, but the term "pharmaceutically active compounds" has been substantially limited to taxol and a camptothecin derivative of the formula disclosed on page 26 of the specification; claims 72-75 correspond to former claims 44-47, claims 76-96 correspond to former claims 51-67 and claim 93 corresponds to claim 70. New claims 94-105 have been added. These claims are directed to a method of transporting an antitumor drug to the target organ, and support for these claims is found in the application as originally filed; see page 8, last two lines. In a preferred embodiment, the target organ is lung of subject suffering a lung tumor; see Example 20 and Figure 3. Claims 102 and 103 are directed to specific embodiments of the invention; see Examples 10-12 and 14-19. No new matter has been added.

Response to Rejection of Claims 29–33, 38-40 and 42 Under 35 U.S.C. §102(a)

Applicants deem this rejection is formulated incorrectly. The rejection is against claims 29-33, 38-40 and 42. The previously pending claims were 43-70, therefore the rejection cannot be against claims 29-33, 38-40 and 42.

This application was filed with a set of claims numbered 29-42; see the Preliminary Amendment of 07/23/2003. With amendment filed on 03/15/2006, claims 29-42 were cancelled and a new set of claims 43-70 was filed. In the Amendment, the correspondence of the two sets of claims was explained. For sake of Examiner's convenience, this correspondence is herein repeated.

New claims 43-53 are based upon previous claims 29-39, where the material being transported is a cosmetic. Claims 61-70 are based upon composition claims 40-42. Therefore, claims 29-33 correspond to claims 43-47, claims 38-40 correspond to claims 52-53 and 61, and claim 42 to claim 70.

Now, with the present amendment, claims 43-70 have been deleted and a new set of claims 71-93 is now under examination.

Claim 71 is novel over Wang et al., since the term "pharmaceutically active compounds" has been restricted to taxol and camptothecin derivatives of the formula shown in the claims. Wang et al. discloses genes, which are patentably distinct from taxol and camptothecin derivatives.

Similarly, claim 86 has the same limitation, but the cosmetically active substance is still present, since undisclosed in the prior art. Withdrawal of the present rejection is respectfully requested.

Response to Rejection of Claims 43-70 Under 35 U.S.C. § 103(a)

Claims 71-93 are now pending. The same considerations on the erroneous citation of the rejected claims made in the previous section of this reply also pertain to this section. Applicants respectfully ask the Examiner to correct the citation and to take into account the claims now pending.

The Examiner considers the claims as obvious in view of Wang, by itself or over Burke '156 or further in view of Stracher '288.

On page 4 of the Office Action, Examiner states the previous rejection over Wang alone has been withdrawn, in view of the arguments previously presented.

Applicants understand that the rejection is maintained over the disclosure of Wang et al in view of Burke by itself or in further combination with Stracher. US 6,008,002 is cited as further support to the rejection.

Examiner states Applicants' arguments were not found to be persuasive, since the claims were generically directed to pharmaceutically active compounds and genes are comprised in the category of drugs. Applicants considered this objection very carefully and found it legally well based. Therefore, claims have been limited to a specific list of drugs, excluding genes. In view of this amendment, this rejection is now moot and should be withdrawn.

The Examiner cites US 6,008,002 as a general teaching on the use of liposomes. This reference deals with cationic liposomes (col. 3, lines 26-28) and teaches macromolecules with an overall negative charge as suitable to form complexes with the liposomes (col. 3, lines 14-20), or macromolecules having a positive charge when previously complexed with an anionic molecule (col. 3, lines 21-25).

The claimed subject matter has now been limited to camptothecin derivatives and taxol. None of the molecules are charged; see the meanings of the various groups in the definitions.

The teaching of this reference is strictly confined to charged drugs, in particular negatively charged drugs, such as nucleic acids (genes), see the same passage mentioned by the Examiner. Therefore, the person of ordinary skill in this art would not have been motivated to try cationic lipids, as taught by Wang et al. or by US'002, to deliver taxol or camptothecin derivatives of the claimed formula. The Examiner will note that the camptothecin derivatives disclosed and claimed in the present invention have no negative charges and the skilled person would be very hesitant and doubtful on the performance of these cationic liposomes in compounds so different from nucleic acids and proteins.

There is no expectation of success in Wang or US'002 for the presently claimed invention.

The Examples in the specification of the subject application show the applicability of the liposomes of the present invention for camptothecins and taxol.

Further, the Examiner cites US 6,171,614 as additional piece of prior art. The present invention, as now claimed, is far from the disclosures of the cited US'614. First, the nature of the liposome is quite different, and the chemical nature of the specific drug now claimed is not comparable with the drugs specifically disclosed in US'614. In fact, this patent gives an enabling teaching only for DNA and peptides.

Without specific information on the applicability of US'614 on camptothecin derivatives of the formula specified in the claims and on taxol, the person skilled in the art would not try liposomes disclosed in the reference. No reasonable expectation of success is suggested.

The art discussed in the specification of the subject application, the art cited by the Examiner and the Examiner himself witness the breadth and complexity of liposome technology and that specific liposomes are studied for specific drugs. In the Office Action, the Examiner argues that the Applicants did not prove the general applicability of their liposomes to the general field of drugs. Now the claims have been limited to the specific teaching offered by the Applicants (see Examples).

As far as the discussion on Burke is concerned, this rejection is also moot in view of the amendments to the claims. Withdrawal is in order.

Burke is a strong signal of what the person skilled in the art knows about liposome technology and expects from it. Burke's liposomes are neutral or negatively charged. This kind of liposome was used in the art for drugs, intended as low-medium molecular weight molecules, such as camptothecins.

The art cited by the Examiner and the art cited in the specification witness the use of cationic liposome only for gene transfer, or at least for macromolecules with an overall negative charge, see US'002. Therefore, there is no indication, teaching or suggestion to the skilled person that a cationic liposome would be suitable for non-charged drugs, such as the camptothecins now stated in the pending claims.

Also the Stracher patent cannot be applied to the teaching of the present invention. First of all, Stracher et al. deal with a different problem, i.e. to target a drug to cardiac and skeletal muscle (col. 1, lines 18-35). This problem is quite different from the one solved by the present invention, namely lung tropism of the anticancer drug (See Example 20). Secondly, the structure of the molecule making up the liposome is quite different. In the present invention, the molecule making up the cationic liposome is an ester of an alkanoyl L-carnitine, in Stracher et al. carnitine is attached to a phospholipid portion. The person skilled in the art knows that the phospholipid will make the liposome, but, according to Stracher et al.'s teaching the L-carnitine is only taught to be the carrier for the drug to cardiac and skeletal muscle.

Stracher et al gives no teaching that an ester of an alkanoyl L-carnitine can make up a cationic liposome, with specific delivery of camptothecin derivatives or taxol to lung tissue.

For the above reasons it is respectfully submitted that claims 71-105 define patentable subject matter. Reconsideration and favorable action are solicited. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100